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(54) **POWER GENERATION FOR IMPLANTABLE**

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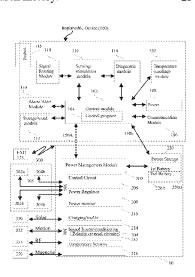
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(57) ABSTRACT

A rechargeable medical system comprised of an implanted device, rechargeable power storage operatively connected to the implantable device, a charging module operatively connected to the rechargeable storage, and external devices including a patient programmer and external charging means. The charging module can harvest at least one of thermal, photovoltaic, movement, RF, and magnetic energy to generate electrical power. The system has components for charging the storage from the generated power, and for measuring power generation, usage and reserve levels. The system provides for physically initiating and disrupting charging operations, for generating and communicating signals relevant to power harvesting, for monitoring, providing, and displaying data related to energy generation and energy generation criteria, and for tracking historical harvesting and energy consumption. The system may also have long-range and shortrange wireless power harvesting capability.

23 Claims, 6 Drawing Sheets



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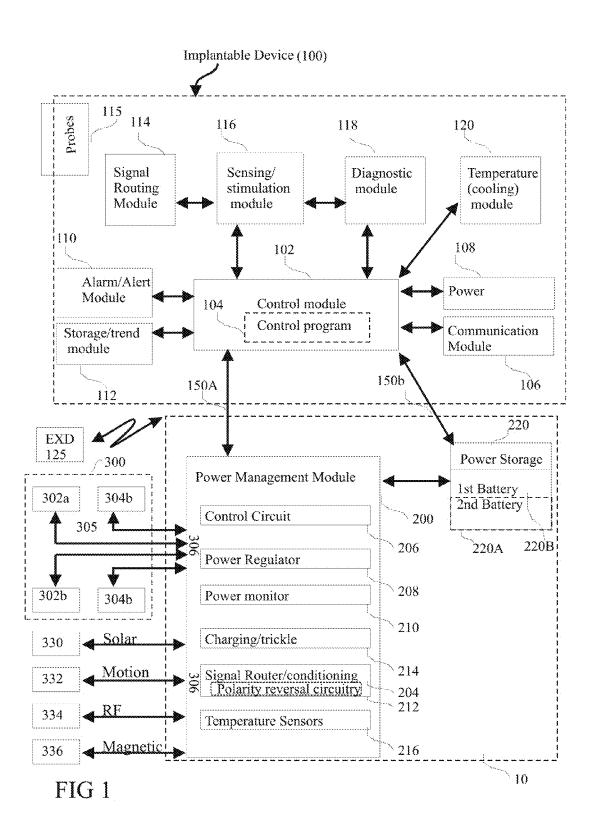
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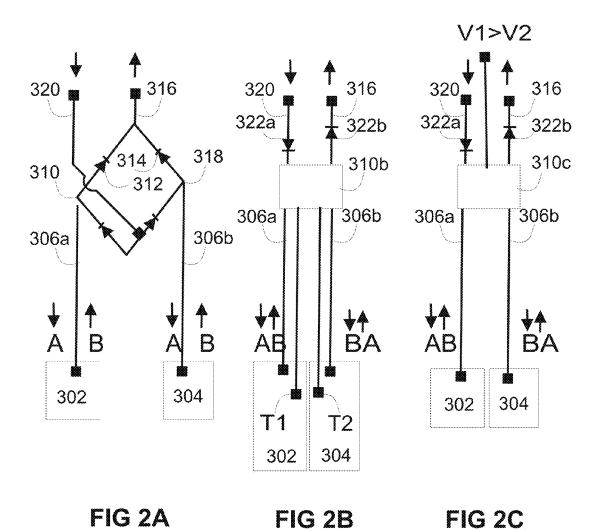
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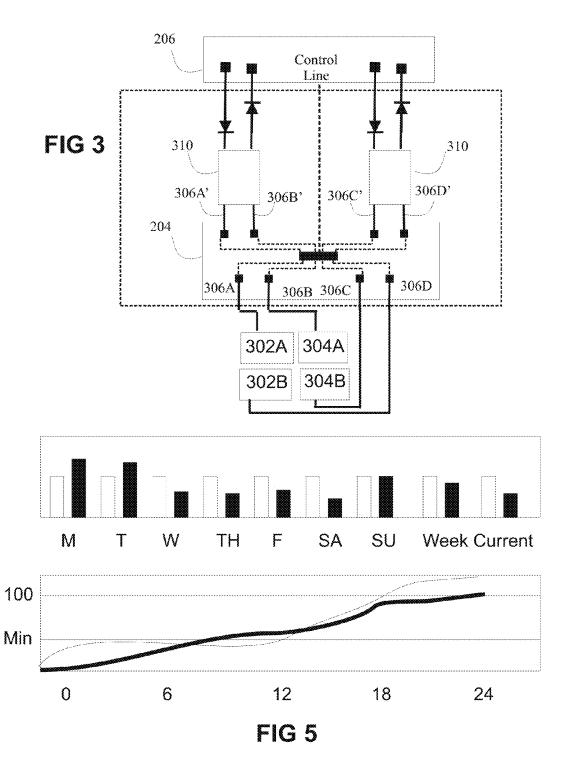
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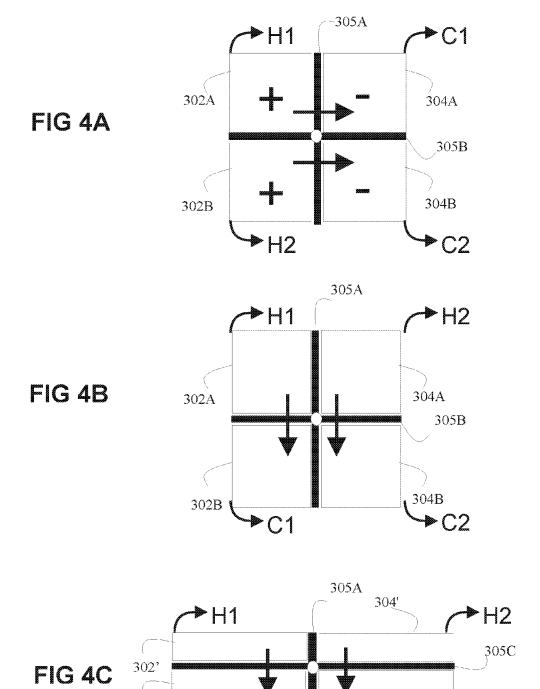






►C2

304"



302"

▶C1

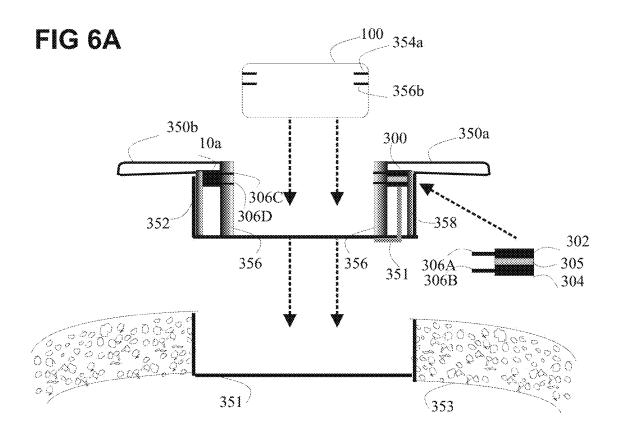
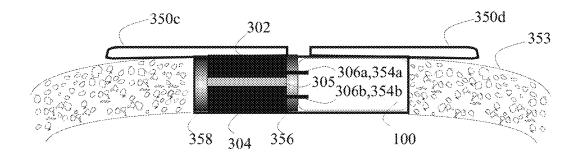
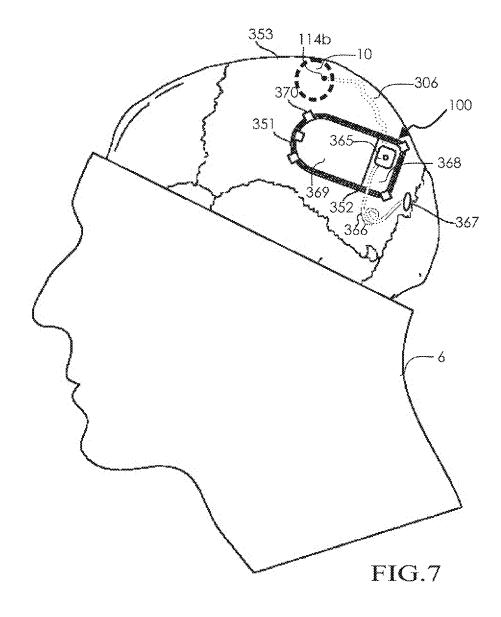


FIG 6B





POWER GENERATION FOR IMPLANTABLE **DEVICES**

This application is a continuation-in-part of U.S. patent application Ser. No. 12/131,910 filed Jun. 2, 2008 which 5 claims priority to U.S. provisional application 60/977,086 filed on Oct. 2, 2007 entitled "Systems and Methods for Wireless Power", 60/941,286 filed on Jun. 1, 2007 entitled "Systems and Methods for Wireless Power", 60/941,287 filed on Jun. 1, 2007 entitled "Power generation for implantable 10 devices", all of which are incorporated herein by reference herein.

The invention relates to providing energy to implantable devices and using wireless energy which has been transmitted and energy derived from natural resources which are avail- 15 able in the patient's environment with an emphasis on utilization of RF energy, heat, light, and motion.

BACKGROUND

Implantable medical devices use electrical power to operate and provide therapies which can include monitoring and stimulation. When therapy is provided or adjusted programmably, using an external patient controller, communication between the external and internal components of the medical 25 system also requires power. An implantable device can monitor the heart and alert the patient when an abnormal cardiac state occurs so that they may seek intervention such as is described in U.S. Pat. No. 6,609,023 and US20070016089, both to Fischell et al. The implantable device may also use 30 this monitoring in delivering responsive therapy such as pacing the heart, delivering a drug, or stimulating nerve tissue of the brain or body as described in U.S. Pat. No. 6,066,163, to

An implantable medical device can be a neurostimulation 35 device which performs sensing and/or modulation of neural activity in the treatment of, for example, epilepsy, motor, pain, psychiatric, mood, degenerative, and aged-related disorders. Neurostimulators can be located in the brain, in the skull, or in the body. This last embodiment will require that 40 electrode leads transverse the neck so that they can stimulate their intended neural targets within the brain. Vagal and cranial nerve stimulators may also be used for therapies related to modulation of the brain or body (as may occur directly or by way of an intervening neural target). Implantable medical 45 devices may be placed throughout the body to modulate the activity of different organs and biological processes, and include devices used in the provision of therapy for eating disorders, pain, migraine, and metabolic disorders such as diabetes. As the duration of sensing, processing, monitoring, 50 implantable device and a power charging module operatively and stimulation increases the amount of power needed will also increase.

The reliability and longevity of a power source is major issue in operating implantable medical devices. Numerous advances have addressed power requirements including 55 improvements in materials, (re-)charging methods, and technologies. Incorporation of dual battery paradigms has also provided benefits since the two batteries can differ in characteristics of energy storage, chemistry and power output capacities, in order to, for example, reach a compromise 60 between high-energy output and sustainability. Implantable devices themselves have also been improved with features such as "sleep" and "low power" modes, where less energy is needed. Regardless of these improvements, all device operations require power, including monitoring, processing of 65 monitored data, stimulation, and communication with external devices.

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A top reason for surgical removal of neurostimulators and other types of implanted devices is longevity of the power source. The need for surgical removal of an entire implanted device traditionally occurs because the battery is integrated into the device itself. This design-related issue can be addressed somewhat by having a separate skull-mounted power module which resides adjacent to the neuronal-stimulator. However, surgery for selective removal/replacement of the power source is still invasive. Further, aside from issues of replacement, in ongoing use of implanted devices, a more robust supply of power can provide improved therapy.

The current invention can incorporate a number of existing technologies such as U.S. Pat. No. 6,108,579, which discloses a battery-monitoring apparatus and method which includes features of tracking power usage, monitoring battery state, and displaying the estimated remaining life of the battery power source. U.S. Pat. No. 6,067,473 discloses a batterymonitoring apparatus and method which includes features of providing audible warnings of low battery life using both tones and pre-recorded verbal warnings of battery depletion. U.S. Pat. Nos. 5,957,956, 5,697,956, 5,522,856, and US 20050021134 to Opie, and 20050033382 to Single, disclose devices having features such as: relatively small mass and a minimal rate of power consumption; means for optimizing current drain; improved shelf storage capacity; minimizing the power requirements of battery power sources; temperature regulation of the power source; and dual battery implementation including use of back-up battery to avoid power disruption. U.S. Pat. No. 7,127,293 to MacDonald describes a biothermal power source for implantable devices and describes methods and materials which are suitable for use in the current invention.

There is a need to provide an improved power supply means for recharging of a power supply of an implantable medical device. Power supply improvements will allow improvements in the performance of the device. Recharging should not require recharging or replacement of the power source in a manner which is unreliable or which places an undue burden on the patient.

The invention provides improved power harvesting, generation and supply and can rely upon naturally occurring sources of energy for at least a portion of its recharging needs. The invention also provides improved power harvesting of transmitted energy.

SUMMARY

A rechargeable power module for powering implantable devices includes a power storage module connected to said connected to the power storage module.

When the power charging module harnesses thermoelectric power, it has at least a first thermal module and a second thermal module which provide power from a thermal gradient. These two modules can be intra-cranially and extracranially disposed, respectively. The power charging module is configured for generating an electrical current from a thermal energy gradient, and for charging said electrical storage module with said electrical current. The rechargeable power module also contains control circuitry for controlling power related operations, as well as charge monitoring circuitry for monitoring rates and levels of charge of the power storage module. The rechargeable power module may also contain alerting circuitry for generating an alert signal whenever the extent to which said electrical storage device is being charged, with said electrical current, falls below a specified value. A disruption module can break the physical connection

between the first and second thermal modules, or between the rechargeable power module an components of the implanted

When the power charging module is a light-based power charging module, it can have at least one extra-cranially disposed surface that is configured for generating an electrical current from said light source (e.g., the sun or a synthetic means), and for charging said power storage device with said electrical current.

When the power charging module harnesses RF energy 10 which is ambient and naturally occurring, or which is actively transmitted by a transmitter device, then an antenna has at least one extra-cranially disposed surface which is disposed for harnessing the RF energy. The energy harvesting antenna may also be used for transmission of data, and can be dis- 15 posed within a ferrule that resides within the skull, within the top side of a neurostimulator device disposed within the ferrule, or within the ferrule itself. When the implanted device is a neurological or cardiac device having leads, then one or more of these leads, as well as sheaths which house the leads 20 can be used, at least a portion of the time, as an antenna for energy or data transmission or reception.

The power charging module may utilize external devices which alter temperature, light levels, magnetic or RF energy available for recharging the power module.

The rechargeable power supply can also contain an alerting module for providing energy-related alerts to a user and a historical charge module which can be configured to generate an alert signal related to power consumption and harvesting. For example, an alert may be sent whenever the cumulative 30 extent to which said electrical storage device is being charged with said electrical current falls below a specified value.

In accordance with some implementations, a wirelessly powered medical system includes: a wireless power transmitter; and an implantable medical device including: a wireless 35 energy harvesting module configured for harvesting at least one type of wireless power; a power management module configured for managing, monitoring, and storing harvested power harvested by the energy harvesting module; a control module configured for controlling the power management 40 module and for creating and storing in a memory module a historical power record, said record comprising at least one of amount of harvested wireless power and amount of power consumed as a function of time; and a communication module configured for providing communication between the 45 implantable medical device and at least one external device. The at least one external device can be an external patient controller configured to provide communication between the implantable medical device and the wireless power transmitter and to display at least one historical value related to at least 50 tion and claims. one of power harvesting and power consumption, the value being based upon data from the historical power record that is communicated to the external patient controller from the implanted device.

patient controller that is configured to display at least one historical value reflecting harvested energy as well as an indicator of a target amount of energy which should have been harvested. The target amount of energy which should have been harvested can be defined as a function of time. The target 60 amount of energy to be harvested can be a value that is programmably defined and adjustable. The target amount of energy to be harvested can be a value that is calculated upon data sensed by a sensor located in the external device. The target amount of energy to be harvested can be a value that is 65 calculated upon data sensed by a sensor located in the external device using a transfer function to estimate the amount of

energy that should have actually been received by the harvesting module of the implanted device.

There are further provided methods for increasing wireless energy recharging capabilities of the system including methods for increasing the thermal gradient used to generate power and increasing the wireless energy harvesting by increasing the wireless energy which is available, received, and harvested by the implantable power harvesting device.

BRIEF DESCRIPTION OF THE DRAWINGS

Features of the invention will be described by reference to the specification and to the following drawings, in which like numerals refer to like elements, and in which:

FIG. 1 shows a schematic diagram of one preferred implantable device for operating using a rechargeable power system of this invention;

FIGS. 2A-2C shows three types of polarity reversing devices that may be used to harness power such as thermoelectric power by the system of FIG. 1;

FIG. 3 shows a diagrammatic representation of a power harvesting module which improves power harvesting related to thermal-based power generation;

FIGS. 4A-4C shows three types of thermal gradients which 25 are applied to thermal modules, and which lead to improved energy harvesting using the routing device of the system of FIG. 3;

FIG. 5 shows an upper plot summarizing energy harvesting levels across a 1 week interval, as well as average and current energy levels and shows a lower plot which can represent the energy harvested over the last 24 hours, the energy harvested as function of time of day averaged over the last week or month, and related plots such as target energy harvesting levels as a function of time;

FIG. 6A-6B show schematic representations of skull mounted neurostimulator devices configured for generating power from a thermal gradient and for efficient thermal regulation of brain tissue; and,

FIG. 7 shows diagrammatic representation of an extracranially disposed energy harvesting device which can be used for increasing the power that is generated using methods generally known as well as those specific to the present inven-

The present invention will be described in connection with a preferred embodiment. There is no intent to limit the invention to the embodiments described. The intent is to generalize the principles disclosed here to all alternatives, modifications, and equivalents as may be included within the spirit and scope of the invention as disclosed within the following specifica-

DETAILED DESCRIPTION

FIG. 1 is a block diagram of an implantable medical device In some implementations, the external device is an external 55 100 and rechargeable power system 10 which in a preferred embodiment functions as a multi-modality charging system, but which may be restricted to a single type of energy harvesting. The implantable device 100 may be similar to many conventional generic implementations of neural or cardiac assistive devices, such as having a control module 102 which implements a therapy as defined in at least one control program 104. The control module 102 controls and communicates with all the other modules of the device 100 in order to provide therapy as intended. Accordingly, under control of the control module 102, the signal sensing and stimulation module 116 provides sensing of data, and stimulation, respectively, from probes 115 operatively positioned within the

tissue of the patient (e.g. electrical, chemical, sonic, or optical probes) or within the device 100 itself (e.g., acceleration, level/tilt sensors, or thermal probes). Sensed data can be analyzed by the diagnostic module 118 which can detect and/or quantify medically relevant events. In response to the detection of medically relevant events, the control module may responsively provide stimulation to a patient 6 or can issue an alert signal such as a sonic signal or a vibration using a probe 115 which is a motor. Alternatively, the device 100 may send an alert signal using a communication module 106 which can provide communication between the implanted device 100 and an external patient device 125 such as a patient programmer device which is implemented in the form of a pager-like device, with a display screen, LEDs, acoustic transducers, and buttons for patient input operations. In addition to memory storage such as RAM and EEPROM, the device 100 can have a storage/trend module 112 which may contain a queriable database, and where information such as parameter values, and historical records related to device 20 operation and treatment may be stored. Temperature regulation (Heating or cooling) both of components within the device 100 or external probes 115 can occur under the control of the temperature module 120. In one preferential embodiment a temperature probe 115 is provided which allows cool- 25 ing of the brain to occur by using a peltier-based probe configured with an extra-cranial heat sink and intracranial cooling surface. A power module 108 may also be provided in order to provide operations related to power management and monitoring, and for storing protocols and parameter values 30 which enable the control module 102 to communicate and control the rechargeable power system 10. Control conduits 150a and 150b are comprised of at least one metallic or optical pathway which provides power and/or control signals to be communicated between the device 100 and the 35 rechargeable power system 10.

The rechargeable power system 10 can harness power using at least one of thermoelectric derived energy 300, solar derived energy 330, motion-based energy 332, RF harnessed energy 334 using far-field and medium-field techniques, and 40 energy harnessed from magnetic fields using near-field techniques 336. When utilizing far-field techniques the modules 334 can be based upon Powercast technology which provides for energy harvesting of both ambient and transmitted energy, and may include at least one antenna and associated harvest- 45 ing circuitry. Some related technologies for transmission and reception, which can be utilized by the current invention have been filed by Powercast and include patent applications for US20070010295, US20060281435, US20060270440, US20060199620, US20060164866, and 50 US20050104453. Some related technologies filed by eCoupled include, for example, Inductive Coil Assembly (U.S. Pat. No. 6,975,198; U.S. Pat. No. 7,116,200; US 2004/ 0232845); Inductively Powered Apparatus (U.S. Pat. No. 7,118,240 B2; U.S. Pat. Nos. 7,126,450; 7,132,918; US 2003/ 55 0214255); Adaptive Inductive Power Supply with Communication (US 2004/0130915); Adaptive Inductive Power Supply (US 2004/0130916); Adapter (US 2004/0150934); Inductively Powered Apparatus (US 2005/0127850; US 2005/0127849; US 2005/0122059; US 2005/0122058. 60 Splashpower has obtained patents such as U.S. Pat. No. 7,042,196. All these patents and patent applications are incorporated by reference herein and describe technologies which will be generally understood herein as wireless power systems that relate to the invention including RF- and near-fieldinduction-related wireless power transmission and wireless power reception.

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The energy harnessing modules 300, 330-336 are connected via the signal router 204 of the power management module 200 to control circuit 206 by leads 306 which provide electrical contact between the harnessing modules 300, 300-336 and the power management module 200. Control circuit 206, in turn, is operatively connected to power regulator 208 circuitry which includes safety and isolation components. The power regulator 208 provides direct current to at least one battery of a first battery 222a, and a second battery 222b of the energy storage module 220. Although only 2 batteries are shown here, many batteries, capacitors, may be used in the power storage module, and these may be stored together, or in physically distinct regions of the device, and even outside of the device. Although the electrical storage module 220 would normally contain at least one battery 222a,b which can be rechargeable, other electrical storage devices can be used such as traditional capacitors or capacitors constructed of carbon, nanomaterials, or other suitable materials. The capacitors can be comprised of multilayer dielectric materials having capacitors and insulators or other type of hybrid compositions (e.g., U.S. Pat. No. 6,252,762 "Rechargeable hybrid battery/supercapacitor system"; U.S. Pat. No. 5,993,996 "Carbon supercapacitor electrode materials"; U.S. Pat. No. 6,631,072 ("Charge storage device"); and U.S. Pat. No. 5,742,471 ("Nanostructure multilayer dielectric materials for capacitors and insulators"). The storage module 220 may be designed without a battery, as may occur, for example, if the power module 108 of the implanted device 100 is to be primarily relied upon or if the device will rely upon external energy sources during its operation.

A power monitor 210 is connected to the storage module 220 and contains sensors for monitoring the power level of batteries 220a,b as well as rates of charge and discharge. The power monitor 210 can cause the power management module 200 to issue an alert signal using the alert module 110 of the implantable device 100 and is capable of providing a warning to a user when the power being generated, stored, or which is in reserve is inadequate. The probes 115 can be used to generate audible, visual, vibrator, or other type of alerts to provide warnings of low battery life. An external patent programmer 125 can display a history of usage, recharging related historical information, and information related to the remaining life of the battery, for example, as may be similar to that shown in FIG. 5.

In a number of preferred embodiments the rechargeable power system 10 relies upon the Seebeck effect which is also known as the "Peltier-Seebeck effect" or the "thermoelectric effect". The Seebeck effect is the direct conversion of thermal differentials to electrical voltage. It is often produced using two junctions of dissimilar temperatures and metals. U.S. Pat. No. 5,565,763 (Thermoelectric method and apparatus') and U.S. Pat. No. 4,095,998 (Thermoelectric voltage generator') describe implementing the Seebeck effect within energy producing devices.

FIG. 1, shows thermoelectric module 300 that has at least a first thermal module 302 and a second thermal module 304, which are connected to the power management module 200 using leads 306. The electrical leads 306 can be routed by a signal router 204 through a polarity reverser 212 prior transmission of these signals to the control circuit module 206. The polarity reverser 212 is used to adjust for the case in which the temperature of a first thermal module 302 is higher than the temperature of a second thermal module 304, and also when the opposite is true. This adjustment is necessary since the polarity of the electric current produced the two situations will be reversed. If the polarity reversal circuitry 212, did not exist then the electrical current produced by the thermoelec-

tric module 300 would not be utilized by power management module 200 in one of either the first or second situation. Various polarity circuit implementations are well known (e.g. see review in U.S. Pat. No. 7,127,293, "Biothermal power source for implantable devices").

Although the device 100 of FIG. 1 may operate alone, when the device is implemented as part of a network of implanted devices, power may be generated, stored, and supplied in a distributed fashion using components which are either within the device 100 housing or distributed. A device which is similar to the BION stimulation device, produced by Advanced Bionics may serve as the device 100. When the device is implemented as a BION, at least one probe 115 can serve to provide sensing or stimulation operations and the housing may serve as a reference or ground source or as part of a bipolar probe. A portion of the BION device can serve as at least one antenna related to wireless power and data transmission. In a device with such small mass and volume, it may be increasingly important to temporally separate charging 20 and non-charging related operations as can occur under control of the control module 102 working in conjunction with the power management module 200. Alternatively, the wireless power transmission device can be synchronized with the BION's operations so that power transmission occurs only 25 during intervals when the BION is not engaged in particular non-charging treatment operations. When a network of BIONs are charged by at least one wireless energy harvesting device, which may be incorporated into a rechargeable power supply, then either a master BION may control operations and 30 allocations of wireless power, or any of the BIONS can communicate requests for or adjust operations related to power harvesting.

FIG. 2A is a schematic diagram of a polarity reversal device 310a that can be used to address opposite temperature 35 differentials that result in forward and reverse currents (which can be implemented within the polarity reversal module 212 of FIG. 1). When lead 306a is negative, electrons flow to point 310, through diode 312, and then through path 316. If the polarity is reversed due to a reversal of the relative tempera- 40 tures of thermal module 302 and 304, electrons will flow through path 306b, through to point 318, through diode 314, and then through path 316. In either case, the temperature difference between the two thermal modules 302,304 will cause power generation. This feature is necessary with bio- 45 logical thermal energy generation since the temperatures surrounding the thermal modules may unpredictably fluctuate both in terms of absolute levels and also relative to each other. This circuit has previously been described in the '293 application.

FIG. 2B shows that the polarity reversal device 310*b* can also be implemented in the form of a router which is guided by a temperature signal from sensors T1, T2 which are placed in the thermal modules and which communicate with temperature sensor module 216, which routes electrical signals of 55 paths 306*a* and 306*b*, to 320 and 316, respectively (or 320 and 316, respectively), depending upon whether T1>T2 or T2>T1. Diodes 322*a* and 322*b* ensure that current flows in the correct directions.

FIG. 2C shows that the polarity reversal device 310c can 60 also be guided by a voltage circuit that can be located in the control circuit module 206 and that tests the voltage produced by connecting paths 306a and 306b to different output paths 320 and 316 and determining which combination results in the maximum desired voltage and polarity. Again diodes 65 322a and 322b ensure that current flows in the correct directions.

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FIG. 3 shows a signal router module 204 which is used to obtain current in a number of different situations which may arise. The router module 204 is connected by leads 306 to thermal modules 302A,B, and 304A,B. Normally thermal modules 302A and 304A serve as a first thermal module and a second thermal module and thereby form a first thermal pair 303A (which is formed conceptually and is not shown). The thermal pair may be positioned in the patient so that 302A is normally more likely to be warmer than 304A. Likewise thermal modules 302B and 304B form a second thermal pair 303B (which is formed conceptually and is not shown). In one embodiment a PNP layer 305A occurs between the first thermal module 303A pair, while another PNP layer 305B occurs between second pair of thermal modules 303B (as shown in FIGS. 4A-4B). The Table 1 shows three exemplary conditions:

TABLE 1

Thermal Probe	Condition 1	Condition 2	Condition 3
302A	38	35	36
304A	35	38	35
302B	39	36	38
304B	36	39	39

Condition 1 shows the four thermal modules with relative temperatures that may occur in "normal" operation. Condition 2 shows temperatures that may occur in an "opposite" operation, where the polarity reversal devices of FIG. 2A-C may be used. Condition 3 shows temperatures which differ by only 1 degree and for which the second thermal pair would require a polarity inverter. In this last instance, using the signal router 204 of FIG. 3, the thermal modules can be re-assigned to form new thermal pairs, notably 302A can be paired with 302B to obtain a difference of 2 degrees (rather than 1), and 304A can be paired with 304B to obtain 4 degrees (rather than 1).

In one embodiment, the voltage produced by thermal pair 1 is combined with the voltage produced by thermal pair 2, by circuitry in the power manager 200. In another embodiment, the thermal modules within thermal pairs 1 and 2 are electronically fused so that 304A and 304B form the "cold" thermal pair (paths 306A and 306C are routed to 306c') and 302A and 302B form the "hot" thermal pair (paths 306B and 306D are routed to 306D'). In this case and the voltage produced is a function of the average differential between these two new functional modules. Combining the output voltages from the two thermal pairs should likely be equivalent to what is obtained by rearranging the electrical paths to form 1 new "combination" thermal pair, but due to real world differences one of these embodiments may perform slightly better than the other. Further, any performance differences between these two strategies can be a function of the ranges of temperature differential, and the power management module 200 can select which strategy is used based upon selected ranges as well as other operational factors (e.g. increased temperature variability in one of the thermal modules).

The power management module 200 can be powered off of the energy harvesting modules 300, 330-336 or by the batteries 220. It is expected that when the temperature differential is greater than 2 degrees Celsius, electrical energy will be produced sufficiently to run the control circuit 206. When the temperature differential is closer to 1 degree Celsius, adequate temperature differential may still be sufficient to provide adequate electron flow to control circuit 206.

FIGS. 4A, 4B, and 4C show a thermal module having 8 thermal plates which can be configured to form a plurality of thermal pairs depending upon the existing temperature differentials. Different thermal pairs are functionally created by rearranging electrical paths 306 so that the different modules 5 are functionally paired (form positive and negative generating components of a circuit). FIG. 4A shows how charge would flow from the left to the right of the thermal module 300' when the plates on the left side of the thermal module are hotter than the plates on the right. When the thermal gradient is reversed, 10 the polarity reversal circuits 310a-310c of FIG. 2A-FIG. 2C can be used. FIG. 4B shows a redistribution of the thermal pairs as a function of the thermal gradient being oriented 90 degrees from that seen in FIG. 4A. In this case, if the same charge pairs were used then there would not be much ther- 15 moelectric output. However, by redefining the thermal modules the functional thermal gradient is increased. The thermal pairs created by 302A and 304A, and 302B and 304B, are redefined as 302A and 302B and 304A and 304B, in order to achieve this novel feature of the invention, wherein electrons 20 travel through PN stack sections which are oriented at 90 degrees to each other. In FIG. 4C, the thermal gradient runs from the top of the thermal module to the bottom, and again, the thermal modules are reorganized so that thermal pairs are created between the top 302' and bottom 302" plates on the 25 left, and right (304' and 304", respectively) side of the thermoelectric module (again an angle of 90 degrees is used to establish a new orientation, but along a different axis of rotation).

Although a square configuration is shown, it is understood 30 that the modules may be of various shapes and sizes, and may be adjusted according to the sites of implantation. Materials may also permit the modules to be constructed so that these have some degree of flexibility. While a single structure is shown in each of the FIGS. 4A-4C, the structures may be 35 imparted within a larger grid structure which may also be square or not. Although illustrated with respect to thermal gradients, and resulting electrical outputs, the same logic would be used in order to utilize the thermoelectric modules as Peltier-based cooling devices, wherein applying currents 40 that if the batteries 220 become completely discharged, the to the different pairs would produce different patterns of heating and cooling. Further, rather than being restricted to thermoelectric generation, other modalities such as light, sound (including ultrasound), motion (i.e. kinetic), and RF harvesting can be used with the systems and methods used by 45 devices shown in FIG. 1 trough FIG. 5 which depend upon displacement of electrical charge in the generation and storage of power.

The PN stacks 305 are here shown as thin layers sandwiched between thermoelectric pairs. The PN stacks can be 50 comprised of several PN layers which are oriented and organized in a number of fashions as is well known. U.S. Pat. No. 6,207,887 (Miniature milliwatt electric power generator') shows FIGS. 12a and 12B indicating that use of smaller PN elements within the PN stacks produces higher output as a 55 function of thermal gradients, and accordingly the PN stacks utilized by the invention may rely upon smaller elements.

Power Management, Reporting, and Control.

The power monitor 210 may use the memory 112 of the device 110 to create a historical record of power generation 60 and consumption such as is graphically shown in FIG. 5. FIG. 5 shows two exemplary plots of the data that may be stored in module 112, as these may be displayed on the external patient programmer 125. The upper panel is a plot of a graph which shows a daily amount of wireless energy that was harvested 65 over the last 7-day period. The white bars represent the daily target which the patient is expected to meet, and these may be

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set, programmably defined, or defined/adjusted, for example, as a function of time, power usage, power generation, treatment needs, or user input. Additionally, in one embodiment, the graph shows the cumulative amounts of power created/ harvested over the entire week (with a change in units of energy) and the current amounts of power in the power storage device. The black bars indicate actual energy created/ harvested. By providing data about historical energy which was created/harvested or used, the patient 6 can gain understand about how daily activities alter power harvesting and usage. The power monitor 210 can also be configured to send alerts when energy harvesting increases above a specified level or drops below a specified level, and a duration criterion can also be used, in order to assist patients in monitoring their energy usage.

In the lower panel of FIG. 5 a graph shows the cumulative power generated/harvested in the last 24 hour period (thin line) as well as the anticipated power which should have been created (thick line). Anticipated or "target" power levels can, for example, have been previously determined by a physician. or can have been computed based upon historical activity of the patient. In this case, the graph shows that from midnight until 6 a.m. the power created was more than the target amount, while from 6 to around noon, the power created was less. By the end of the day the patient has generated/harvested a surplus amount of power compared to the target amount (100%), and has well surpassed the target power generation level, which may be a minimum threshold limit value.

In order to keep the battery 220 from becoming discharged below a particular level the alert module 110 can issue alerts when power levels become critically low so that the patient will make certain that the battery 220 is recharged in the near future. The alert module 110 may also be configured to shut down the device 10, or portions of the device 10, or to limit operation to certain functions defined as a lower power state, when a particular critical level is reached so that there is enough energy to perform essential operations, such as operations relating to recharging the battery.

The re-chargeable power module 10 can be configured so module 10 can supply emergency power to the device 100, or can initiate recharging operations using purely wireless power harvesting, if sufficient wireless power becomes available. This type of restart operation can also comprise marking the occurrence of a complete system shutdown in the storage module 112. When a minimum battery power is reached the storage module may store the time of the shut-down in memory of module 112. Accordingly, upon restart, the current time and date can be re-established using an external patient device 125, in order to calculate how long the device was non-functional. Storing power 'shut-downs' and 'restarts' in the historical module 112, may also lead to the generation of an alert signal being sent by the alarm module 110, to a central station which the device communicates with using the communication module 106. This is important since if patients are non-compliant with respect to ensuring sufficient energy harvesting, then the implanted device will not provide much therapeutic benefit. Unlike implantable devices which use very little power, when implantable devices are configured to use more energy, it is important that the patient is compliant in ensuring that energy harvesting is sufficient for proper system operation.

In one instance, if the patient had not generated more power than indicated by the "minimum power generation threshold level" by a selected time (e.g. 6 p.m.) then the alert module would have issued an alert signal to the patient. Rather than displaying results for the last 24 hours, the graph could have

been computed upon charging patterns calculated for other prior periods such as the last week or month. In this manner the patient can learn about, for example, how daily activity influences temperature around the thermal modules and can increase their subsequent ability to charge the implanted device as needed. In addition to power generation, other data can be displayed including power usage, temperature of thermal modules, and differential temperatures of thermal pairs (as well as the pairs that were created).

Alert signals can be generated in order to warn the patient when battery power becomes lower than a specified amount, when the average rate of power consumption is more than the rate of power generation for a selected interval, when the slope of residual power by time has a value that is more than a selected level for a specified amount of time, as well as numerous other characteristics related to charging, discharging, and residual power supply. Alerts can also be generated if the temperature as recorded from thermal sensors 115 near thermal modules 300 indicate that temperatures are outside of a normal range for an extended amount of time, for example, in a manner that is not beneficial to generating power in an expected fashion.

Power management and control provided by the power management module 200 is needed for disentangling power 25 related operations from other operations of the device 100. It is likely that in devices 100 which utilize sensing, certain sensing operations should be halted, delayed, attenuated, or otherwise modified during a portion of the charging operations, and subsets of steps related to carrying out these operations, especially if the wireless harvesting includes near-field induction transmitters. In devices 100 which utilize stimulation, certain stimulation operations should be halted, delayed, attenuated, or otherwise modified during a portion of the 35 charging operations, and subsets of steps related to carrying out these operations, especially if the wireless harvesting includes receiving energy which is above a specified level. In devices 100 which utilize communication with external devices, certain communication operations should be halted, 40 delayed, attenuated, or otherwise modified during a portion of the charging operations, and subsets of steps related to carrying out these operations, especially if the data communications include alerting and/or transfer of diagnostic data related to an alert signal. In devices 100 which utilize sensing, 45 stimulation, or communication, transmission of wireless power or power harvesting operations should be halted. delayed, attenuated, or otherwise modified during a portion of the non-recharging operations, and subsets of steps related to carrying out these operations.

Additionally, the re-charging circuitry may be configured to work with the sensing, stimulating, and communication circuitry so that various charging operations and related phenomena which are influencing the sensing, stimulation, or communication subsystems of an implanted device are 55 ignored, compensated for, or otherwise addressed by these subsystems, and associated operations and algorithms. This type of compensation may occur, for example, using communication between the power management module 200 and the sensing/stimulation 116, communication 106, or diagnostic 60 118 module. Selected non-charging operations can occur simultaneously with charging operations when filters and circuitry are provided to isolate the effects of charging-related operations and treatment related operations. For example electrical artifacts due to charging can be filtered out, sub- 65 tracted, or made to occur in a time locked manner so that the artifacts occur in a controlled rather than spurious manner.

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Thermal Issues of Energy Harvesting, Usage, Storage, and Stimulation

Some preferred embodiments of implanted medical systems which include neurostimulators, ferrules, rechargeable power supplies, and thermal-cooling are shown in FIGS. 6A, 6B, and 7. In FIG. 6A an extra-cranial receiver plate 350a which approximately conforms to the skull may be used to disperse heat away from a skull mounted implantable device 100, which in this instance is a neurostimulator device which resides within a ferrule 352. A thermal module 300 having a thermal pair 302,304 which are separated by a PNP layer 305 supplies power to the device 100 using electrical conduits 306A, and 306B, which will supply voltage in one direction, or the other, depending upon whether one side 302 of the thermoelectric module 300 (which receives or dissipates energy via the extra-cranial receiver plate 350a) is hotter or cooler than the other side 304 (which receives or dissipates energy via the intracranial-cranial receiver plate 351). The power is communicated to the device 100 by electrical contacts 354a, 354b which, respectively, are in contact with electrical conduits 306A, and 306B, which travel through an inner thermal and electrical insulation layer 356. An inner thermal and electrical insulation layer 356, and an outer insulation layer 358, as well as additional insulation layers can be implemented within the device to insulate various components against unwanted thermal and electrical coupling. In one embodiment, the device 100 is normally recharged using solar or thermal means, but when these are insufficient the patients are alerted 110 so that they can charge the device using an external means. In the case of thermal plates 302, **304**, the patient can apply a heating or cooling device directly to their skull. In the case of a photovoltaic (i.e. 'solar') energy harvester, patients can go outside into the sun or can apply a light (laser) to their skull.

In FIG. 6A, an extra-cranial receiver plate 350b which approximately conforms to the skull may be used to harness energy using a number of wireless modalities (e.g., light, temperature, sound, RF, induction). It may be configured not only with thermal plates 302/304 and a PN stack 305, but also with solar components 330, motion-based electrical generation components 332 (including sound/vibration harnessing modules), RF components 334, and/or magnetic induction components 336. The receiver plate 350b may comprise one or more skull mounted induction coils, skull-mounted RF antennas, photovoltaic cells, and the like. Utilization of an extra-cranial receiver plate 350b, provides energy harvesting which is more efficient than systems which require that radiant energy travel an increased amount of distance, and through both skull and tissue, in order to reach receivers located intra-cranially. In one embodiment, the device 100 is normally recharged using solar or thermal means, but when these are insufficient the patients are alerted 110 so that they can charge the device using an external means. In the case of an RF or magnetic induction receiver, the patients can act so that the wireless energy transmitter is turned on or brought into sufficient proximity to the receiver 334, 336. The use of skull mounted receiver plates 350a is advantageous because these can be larger than that which might exist when positioned in other parts of the brain or body. Accordingly receiver plate 350b as well as a rechargeable power supply 10a capable of energy harnessing, conversion, and storage of energy can be located distal from the ferrule 352 or device 100, and can send energy to the device 100 via electrical conduits 306C, 306D. For example, a skull mounted photovoltaic device that retained within a distally located receiver plate 350c (similar to that seen in FIG. 7), which resides upon a patient's frontal skull portion (i.e. 'forehead') is well posi-

tioned to receive light and may reside across a 1 inch by 1-2 inches area without causing the patient discomfort. The ferrule 352 is configured for residing in a surgically prepared area 351 of the patient's skull 353.

In the case where the receiver plate **350***b* serves as an 5 induction harvester, it may be divided into at least a first portion and a second portion, each of which may be electrically and thermally insulated from each other, which may make functional (data or power) communication with external devices (and appropriate polarities) and which may further make respective electrical connection with skull mounted components, or a ferrule which communicates with the device, or at least one implanted device itself.

Energy harvesting circuits and antennas can be configured to receive RF energy, or wireless energy which has positive 15 and negative charge polarities. When these components are encased within a metal such as titanium (i.e. when these are within the housing of an implanted device), this encasement may be designed with partitioning, non-conductive, and insulating materials which are disposed within the housing material so as to permit differential charges to be induced on the energy harvesting circuits and antenna's (i.e. in order to circumvent or attenuate field dispersion and isopotential surfaces). Alternatively, the receivers may be independently housed and connected to the implanted device in a manner 25 which enables electrical isolation so that shorting, grounding, and isopotential gradients do not hinder wireless charging functionality.

FIG. 6B shows an embodiment of the invention in which a thermoelectric module 300 and device 100 are disposed in an 30 adjacent horizontal configuration. Energy can be created when the thermoelectric module experiences a temperature differential between the a first element 304 which is on the ventral side and which obtains heat from intracranial sources, and a second element 302, which is disposed dorsally and 35 which can further distribute heat along the energy reception plate 350C. Charge crossing the PN stack 305 causes current to flow through conductive conduits 306A, 306B an into the device 100 through electrical contacts 354a,354b. The PN stack 305 can consist of a multiplicity of n-doped/p-doped 40 thermocouple pairs preferably electrically arranged in series and sandwiched between ceramic plates, although any configuring is possible (e.g., U.S. Pat. No. 6,207,887, but which use different separator elements between the P-type and the N-type elements. Thus, one may utilize epoxy-impregnated 45 paper isolators; see, e.g., U.S. Pat. Nos. 3,780,425 and 3,781, 176). Alternatively, if the device supplies current to the thermoelectric module 300, rather than receiving it, then it can produce heating or cooling of the first and second elements 304,302, depending upon the characteristics of the current 50 flow. In this case the device 100 may produce heat, due to discharge of the battery in order to provide the thermal stimulation (i.e. cooling or heating of the brain). Energy reception plate 350d can be configured to transfer heat away from the device 100. Alternatively energy reception plate 350D can be 55 configured to provide additional forms of wireless energy harvesting and can contain some or all of the necessary components to achieve this (although not shown, electrical conduits 306 C-E, and electrical contacts 354C-E can provide power and communication to be exchanged between energy 60 receiver plate 350d and the device 100). Additionally, energy reception plate 350C can be configured to harness wireless energy and to supply energy to the thermal module in order to provide, for example, cooling of the brain.

FIG. 7 shows a rechargeable power supply 10 which is used 65 for recharging a battery, for providing energy to a device 100, or for providing energy during thermal cooling of the brain

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which is disposed partially or fully in an extra-cranial location that is remote from an implanted device 100 which here is a neurostimulator. Energy harvesting and recharging as well as cooling-based neurostimulation therapy can produce heat as a by-product. Further, the discharge of a battery which is supplying power during thermal stimulation (i.e. neural-cooling) can result in heat generation within the battery. Deployment of the re-charging receiver plates 350c upon the patient's skull and otherwise removed somewhat from the device itself is advantageous since implanted devices often use the device "can" as a ground to which electrical sensors are referenced. Because charging operations may encounter relatively large fluctuations in power generation and storage, as well as thermal fluctuations, these should likely occur some distance from the device 100 itself.

FIG. 7 shows an embodiment of the invention in which a distally located wireless energy receiver module 350C, may be configured as an energy harvesting device 10 having modules such as 300, 330-336, and which contains a signal routing module 114b, for transmitting data and power through electrical conduits 306, and to device 100. When the energy harvesting device is a thermoelectric module 300, then energy can be created when the thermoelectric module experiences a temperature differential between its first element 304 which is on the ventral side and which obtains heat from intracranial sources, and a second element 302, which is disposed dorsally. Charge crossing the PN stack 305 causes current to flow through conductive conduits 306 an into the device 100 through electrical contacts housed under the electrical connection module 365. Electrical connection module also serves to connect a proximal side of neuron-stimulation leads 366 to the device 100, so that the distal side can be fed through burr hole 367 and into the brain of the patient. The device 100 may reside within a ferrule 352, which has been inserted in a prepared portion of the skull 351, and which is affixed to the skull with connection tabs 370. A first device cover 368 and a second device cover 369 can house the device components, and can also serve as energy harvesting antenna, or other components of the wireless energy harvesting modules. It is advantageous to have wireless energy harvesting devices (e.g. thermoelectric charging module) be remote from the neurostimulator since these may generate heat or conduct heat in a manner which makes the first and second surfaces similar in temperature.

It is one advantage of the current invention to provide an extra-cranially situated power harvester and/or rechargeable power supply which powers an intra-cranially situated, or skull mounted, device 100 which may be a neurostimulator. In a preferred embodiment, a portion of the recharging power related components are situated at least 0.5 inches away from the implanted device.

Wireless Energy Transmission and Reception Strategies.

Generally, the power received decreases with the amount of distance between the wireless transmitter and the receiver. While a skull mounted receiver plate 352 can assist in energy transfer with neurostimulation electrodes, when the implanted device is a cardiac-related device such preferential disposition of an wireless energy receiver such as an antenna will not help much. The transmission of energy, rather than energy reception, can have improved features which can assist in increasing wireless energy harvesting. A number of embodiments can serve to decrease the transmission distance and to increase patient compliance with respect to maintaining adequate charge levels.

In one embodiment the power transmitter can be implemented within modified versions of commonly used objects such as furniture. For example, a power transmitter can be located within:

a. a back of a chair and further with the transmitter situated 5 approximately adjacent to the patient's upper torso;

b. a mattress or mattress cover and further with the transmitter situated approximately adjacent to the patient's upper torso:

c. a wearable vest, and further with the transmitter situated 10 approximately adjacent to the patient's frontal and rear torso section:

d. an article of clothing such as a chest strap, brassier, wristband, armband, headband, or hat;

e. a blanket, blanket cover, or sheet, and further with the 15 transmitter situated approximately adjacent to the patient's upper torso; and,

f. a seat cushion configured to overlap or be attached to the back support portion of a chair and further with the transmitter situated approximately adjacent to the patient's upper 20 torso.

Because it is wasteful to operate these types of power transmitters continuously, power transmission may be linked to a sensor which will automatically toggle the state of the power transmission. For example, a wireless power transmit- 25 ter which is realized within a back of a chair may further comprise a motion sensor module, a temperature sensor module, a light sensor module, or a pressure sensor module, any of which may be used to determine if an individual (e.g., a patient with an implanted device) is sitting in the chair. The 30 wireless power transmitter may also contain a sensor module which can receive an RF, sonic, or other signal from an implanted device that it is within the vicinity of the wireless power transmitter so that wireless power transmission may be initiated. The wireless power transmitter may also include a 35 timer or real-time clock so that power transmission can occur for a selected amount of time, a selected amount of time after a patient activates a sensor module, during specific times of the day, and otherwise in manners that can be programmable and adjustable by the patient or a medical practitioner.

Although wireless power may be provided using far-field (e.g., RF) energy transmission, the above features can be implemented with transmission of other forms of wireless energy such as heat, light, induction, near and medium field transmission. In fact, induction type wireless charging is 45 probably better suited for charging implanted devices if these are close enough to a body surface of the patient. Further, cooling devices may also be utilized in order to assist in thermoelectric power generation.

Wireless energy utilization can be realized by the implant- 50 able device using relatively new technologies for receiving the energy. Such technologies are related to inductive and far-field means of transmission and reception and include transmission by radiofrequency energy, thermal energy, sound energy, and other sources radiant energy. Schemes to 55 achieve wireless energy transmission and harvesting is disclosed in US 2006/0281435 for 'power devices using RF energy harvesting', US20060270440 for a 'power transmission network' and a set of related disclosures filed by Shearer et al. and Greene et al, and which describe technology known 60 as Powercast. The Powercast technology can be used for both transmission and reception (harvesting) of transmitted energy or of ambient energy such as radio-wave energy which is present in the devices environment. The Powercast technology can capture wireless energy using both near-field (e.g. 65 inductive) and far-field transmitters. Alternative transmission-harvesting strategies have been described with sound or

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other energy types (e.g., U.S. Pat. No. 6,858,970 for a 'multi-frequency piezolelectric energy harvester', US 20050253152 for 'Non-contact pumping of light emitters via non-radiative energy transfer'), or resonant energy harvesters comprising resonant power antennas which tuned to the power transmitter's (beacon's) frequency in order to accomplish "nonradiative resonant energy transfer" (e.g. Soljacic et al. 2006, http://web.mit.edu/newsoffice/2006/wireless.html).

In order for implantable devices to effectively operate using wireless energy a number of considerations must be addressed. Firstly, the issue of energy reception should be addressed. When the energy harvesting module utilizes antennae larger volumes may be associated with improved energy capture. Further, although one energy harvester may be utilized, joint utilization of a plurality of harvesting modules can increase the amount and stability of the supplied power. Implanting the harvesting modules within the patient should be limited by issues related to implantation and explanation of the devices, patient comfort, and energy reception. Generally, the deeper implantation results in a corresponding decrease of energy reception for an equivalent amount of transmitted energy.

The human skull provides a unique location for implantation of energy harvesting components, including an antenna. In contrast to intracranial located positions, the surface of the skull provides a relatively large surface on which device components may reside. A skull mounted energy harvesting module has a number of benefits such as increased heat dissipation, increased energy transfer due to less intervening tissue, and increased capacity for retaining larger components. A preferred embodiment, skull mounted energy harvesting components may be configured according to the contours of a particular patient's skull, can be constructed in a flexible manner so that these may bend to the shape of the skull, or may be constructed in sections that are flexibly held together and which permit cooperation with the contour of the skull. The skull mounted energy harvesting device components can reside within a flexible and biocompatible material such as a silicone based sealant, or the like (Medtronic US20060184210 entitled 'explanation of implantable medical device'). In another embodiment, an implantable or intracranially residing neurostimulator is powered by an extracranially and approximately skull mounted harvesting device. In another embodiment, an implantable or intra-cranially residing neurostimulator is powered by a cranially residing skull mounted harvesting device, which may be affixed directly within the skull or indirectly via a ferrule device. Two or more energy harvesting devices, or related antennae, may be mounted bilaterally, over opposing hemispheres or split between frontal and posterior locations. The two or more antennae may be related to different uses such as wireless transmission/reception of data and power, respectively. Antennae may consist of various electroconductive harnessing substances such as metal, water, saline, saline laced with metallic flakes, or other suitable medium.

In one embodiment, recharging is halted or adjusted when non-charging operations such as sensing or stimulation operation are to occur. During sensing, this may be done in part to reduce any distortion of the sensed signals. For example, if the 'can' is serving as a ground for a mono-polar electrode, then if sensing occurs simultaneously with charging operations then the energy fluctuations associated with charging operations could distort, contaminate, or otherwise shift the recorded potentials.

For this reason, or due to other considerations, the implanted device could be triggered to send control commands to the wireless power harvester modules to turn energy

harvesting 'on' or 'off'. Alternatively and additionally, the implanted device could send control commands to the wireless power transmitter to turn energy transmission 'on' or 'off', or can request that energy transmission be temporarily decreased or increased, or otherwise adjusted. Rather than 5 simply shutting off, a temporarily increase or decrease can occur as a specified ramp-down or ramp-up function which may be related to charging operations or direct power supply to a in implanted device. Further, there can exist a "sleep" function which causes the power transmission to be stopped 10 for a pre-defined amount of time before it is automatically restarted. In this manner, energy is not wasted by requiring the implanted device or the external patient programmer to send a 'restart' signal.

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Rather than requiring the implanted device to send commands directly to a wireless power transmission device, the implanted device can control the wireless power transmitter indirectly through the external patient controller, which can be configured to communicate with the power transmitter as well as the implanted device. Additionally the external patient 20 controller can be configured to send control signals to the wireless power transmitter in order to alter its activity, so that it may better perform its own operations. For example, the external patient controller can send control signals to the wireless power transmitter before it initiations communica- 25 tion with the implanted device or sends commands to the implanted device to initiate operations requiring stimulation or sensing. Rather than requiring wireless power companies to provide specialized transmitters that can receive commands from an external patient device, the wireless power 30 transmitter can be power by a mains source which is fed to it by a programmable power supply created by a medical device manufacturer. Accordingly, a wireless power transmitter can be used, and a level of control can be obtained by controlling the power fed to the transmitter itself.

In one embodiment, the implanted device can provide alerts and status indications for level and power related characteristics such as the amount of power recently obtained, present power levels, or present strength of reception. Alternatively, or additionally the external patient programmer can 40 also be configured with a wireless power harvester and/or 'power monitor' module adapted to measure the strength of transmitted energy that is being received, the amount of energy being harvested, or an energy profile which can contain an estimation of energy present at different wavelengths 45 (e.g. a spectral profile of energy). Although the energy implanted wireless power components and external wireless power components may receive different amounts of energy, "Eint" and "Eext", respectively, these two amounts can be compared and a transfer function can be used to estimate the 50 amount of energy actually received by the implanted harvester.

Additionally, the external patient controller can contain a "power profile" module which can adjust the amount of remaining "estimated power" for the implantable device by 55 subtracting power which it estimates the internal device is consuming based upon the basal rate of energy usage of the device, notices it obtains from the implanted device that it has performed operations such as stimulating, and commands sent to the implanted device by the external device such as 60 commands related to changing power state (e.g. going into a sleep state or commands to initiate stimulation or sensing operations).

Although the implanted wireless power harvester module may operate in a fixed manner, it may also adjust the characteristics of the harvester module in order to generate power from different frequencies of wireless energy which are 18

present. The energy reception parameters can be adjusted to bias the reception of frequency specific energy so that reception of selected frequency ranges are facilitated or blocked. The energy harvester can utilize reception parameters which can be adjusted to match the frequencies of the energy which is received with the profile of energy being transmitted by a wireless power transmitter. This may occur because in different locations, different transmission profiles, reception profiles, or transmission-reception profiles will allow energy transmission, harvesting, or both to occur more efficiently or reliably or to provide different amount of energy as may be required by the implanted device. Further, when ambient levels of energy are relied upon, rather than wireless power transmitted energy, the spectral profile of the ambient energy may change over time and in different locations. Although the implanted device may automatically adjust the parameter of its harvesting module (which may occur with changes in the energy transmitting module) in order to adjust (i.e. improve) energy harvesting operations, this may require energy and could result temporary energy decreases (e.g. if an unsuccessful profile is selected). Accordingly the external patient programmer may perform these optimization/calibration processes and then use the results of these operations to adjust the characteristics of the implanted energy harvester.

Calibration test-signal procedures can be implemented when normal energy harvesting is not occurring. Additionally, in addition to using the external patient controller, an energy monitoring device (or only a sensor component) may be worn as a watch, or, in the case of a neurostimulator, can be incorporated into a person's hat or eyeglasses in order to sense energy fields which are similar to that which will be experienced by the implanted device.

Energy profile sensing can occur within the implanted or external energy monitoring devices in order to adjust parameters related to energy harvesting and increase or stabilize energy reception. While radiowaves may often be a main source of energy for the wireless power harvester device, if a patient is located in an area with larger sources of energy, then the wireless power harvester should be adjusted accordingly. For example, Extremely low frequency (ELF), voice frequency (VF), and very low frequency (VLF) may be ambient in an environment at higher levels than radiofrequency. Such an example occur in the case where a patient is situated in front of a television, so that 50 or 60 Hz line noise, and possibly the refresh rate of television screen, as well as the subharmonics and harmonics will be larger than radio-wave energy. At least one component of the energy harvester module should be configured to capture this type of energy and its harmonics. If the patient is outdoors in the country, then radiowaves may be larger than sources of 60 Hz, and the receiver should be tuned to optimize capture of this different energy profile. Additionally, the wireless power harvester module may contain two different harvesting circuits (e.g. including antennae and resonators) which are both active so that energy can be harvested at these very different locations of the electromagnetic spectrum.

The entire disclosure of all cited references including United States patents, applications, websites, and technical/scientific/engineering publications are hereby incorporated by reference into this specification as if fully recited herein. Using similar design features such as electrical or optical connections will be obvious to those skilled in the art, and it will also be obvious to those skilled in the art that the wireless power generation modules and process described herein may be scaled either up or down in size to suit power requirements of specific implantable devices. Any of the aforementioned

changes may be made in the apparatus without departing from the scope of the invention as defined in the claims.

All section titles are provided for convenience and are merely descriptive and thereby are not intended to limit the scope of the invention.

What is claimed is:

- 1. A wirelessly powered medical system comprising:
- a wireless power transmitter; and
- an implantable medical device comprising:
- a wireless energy harvesting module configured for harvesting at least one type of wireless power;
- a power management module configured for managing, monitoring, and storing harvested power harvested by the energy harvesting module;
- a control module configured for controlling the power management module and for creating and storing in a memory module a historical power record, said record comprising at least one of amount of harvested wireless power and amount of power consumed as a function of ²⁰ time; and
- a communication module configured for providing communication between the implantable medical device and at least one external device.
- **2**. The system of claim **1**, wherein the external device is an ²⁵ external patient controller that is configured to provide communication between the implantable medical device and the wireless power transmitter.
- 3. The system of claim 1, wherein the external device is an external patient controller that is configured to display at least one historical value, the value being related to at least one of power harvesting and power consumption, said value based upon data from the historical power record that is communicated to the external patient controller from the implanted device.
- **4**. The system of claim **3**, wherein the at least one historical value is a historical record of the amount of energy that was harvested by the device as a function of time.
- 5. The system of claim 3, wherein the at least one historical value is a historical record of the amount of energy that was 40 consumed by the device as a function of time.
- **6**. The system of claim **3**, wherein the at least one historical value is a historical record of wireless power harvesting calculated for at least one prior period that is selected to be at least one of a prior day, week, and month.
- 7. The system of claim 3, wherein the at least one historical value is a historical record that includes usage patterns calculated for prior periods including at least one of the prior day, week, and month.
- **8**. The system of claim **1**, wherein the external device is an external patient controller that is configured to display at least

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one historical value reflecting harvested energy as well as an indicator of a target amount of energy which should have been harvested.

- **9**. The system of claim **8**, wherein the target amount of energy which should have been harvested is defined as a function of time.
- 10. The system of claim 8, wherein the target amount of energy to be harvested is a value that is programmably defined and adjustable.
- 11. The system of claim 8, wherein the target amount of energy to be harvested is a value that is calculated upon data sensed by a sensor located in the external device.
- 12. The system of claim 8, wherein the target amount of energy to be harvested is a value that is calculated upon data sensed by a sensor located in the external device using a transfer function to estimate the amount of energy that should have actually been received by the harvesting module of the implanted device.
- 13. The system of claim 1, wherein the control module is further configured to control an alert module to provide an alert if energy harvesting increases above a specified level.
- 14. The system of claim 1, wherein the control module is further configured to control an alert module to provide an alert if energy harvesting decreases below a specified level.
- 15. The system of claim 1, wherein the control module is further configured to control an alert module to provide an alert if energy harvesting decreases below a specified level for at least a selected duration.
- 16. The system of claim 1, wherein the control module is further configured to control an alert module to provide an alert if energy harvesting fails to meet at least one energy generation criterion.
- 17. The system of claim 1, wherein the control module is further configured to adjust operation of the implanted device, when the power falls to a selected critical level.
- 18. The system of claim 1, wherein the control module is further configured to shut down to a low power state, when the power falls to a selected critical level.
- 19. The system of claim 18, wherein the control module is further configured for storing power 'shut-downs' and 'restarts' in a memory module, whereby a record of insufficient energy harvesting is created.
- 20. The system of claim 1, wherein the transmitter is configured for resonant energy transfer.
- 21. The system of claim 1, wherein the energy harvesting module is configured for resonant energy harvesting.
 - **22.** The system of claim 1, wherein the energy harvesting module is configured for RF energy harvesting.
 - 23. The system of claim 1, wherein the external device is configured to provide communication between the implantable medical device and the wireless power transmitter.

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